HealthManagement.org The Journal

LEADERSHIP • CROSS-COLLABORATION • WINNING PRACTICES

ISSN = 1377-7629

VOLUME 19 • ISSUE 3 • 2019 • € 22

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Personalised Medicine: The road ahead

How can healthcare accelerate the implementation of the science?

Where is Personalised Medicine (PM) already improving the lives of patients and what is needed to make it the standard of care across multiple conditions?

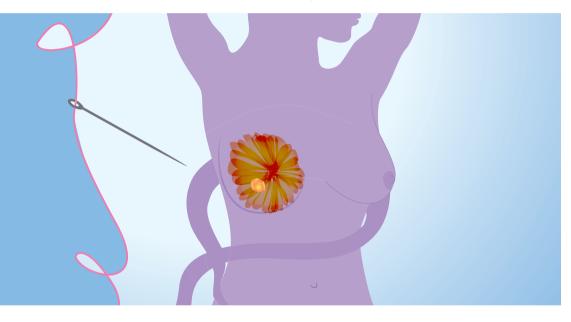


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What's your brief at the PMC?

I have a science and genetics background and bring scientific expertise to the PMC. I'm leading the programme and initiatives that try to make a case for PM, show scientific validity, understand trends and show how to implement it in clinical care. Alongside my work, the public policy portfolio works with different policymakers throughout Washington DC.

Together our goal is to advance PM, facilitate access to PM for patients and help healthcare providers implement it.

The potential of genomics and PM, for example, with the Human Genome Project (HGP) has been presented as having huge potential for tailoring and improving healthcare. However, some critics claim that PM is not delivering on its promise and funds would be better spent on population **health. Can you please cite two or three examples of where PM is already making a tangible impact?** The HGP and the growth of the tech in the field is something that is ongoing and, as more technologies are developed and beginning to be implemented in healthcare, we are seeing an increased rate of technology implementation and development. The PMC strongly feels that PM is the future of medicine and we need to establish the environment for it. It has already made an impact in several areas.

Firstly, we have seen utility in breast cancer with the use of biomarkers that identify candidates for targeted therapies in care. This has been so beneficial in treating patients, it has now become the standard of care in breast cancer therapy. For those patients who have certain biomarkers that make them eligible for targeted therapies, the long-term survival rates have increased dramatically and breast cancer is less of a death sentence than it used to be. It is now more of a chronic disease.

Outside of the oncology space, there is progress with cystic fibrosis. This is a rare disease where patients have difficulty in clearing mucus from their chest and have a long progression into a continuously degenerative lung situation that, previously, had led to very early deaths and a difficult end. Today, because of testing and understanding the 'biomolecular' pathways for this condition and development of new therapies that target those pathways, the vast majority of cystic fibrosis patients are getting targeted treatments that have allowed them to live normal life spans and to breathe freely.

A therapy that is relatively new but is showing remarkable benefits to patients is gene therapy for retinal disease. This has allowed patients with inherited degenerative vision disorder to regain sight by directly targeting the gene that is mutated in the molecular pathway that leads to disease.

Is PM scalability a challenge and, if so, what are some ways you are seeing healthcare organisations overcoming this?

It's certainly a problem. In a lot of areas we are seeing PM being implemented or inducted through pilot protocols (which are really research protocols). Scaling that to become regular care in healthcare and care delivery systems has been a clear challenge. IT management has played a huge role in the strategies that are bringing PM research to regular care. Sometimes there are massive amounts of data involved in PM therapeutics strategy and this has to be integrated into the system. It's important that accurate information gets to the physician through a clinical decision support mechanism. The aim is that it's ultimately a net time save for decision making. As with all new technologies, there is inevitably a lag time as physicians begin to understand personalised medicine and how to implement it and there's reluctance by many to do things differently until they know that it works. We need to make sure that the IT management systems are in place that can bring PM forward. This is already directly linked to EHR integration.

With your experience and insights into the practicalities of PM, what would you say to any critics of this healthcare movement?

I don't think that there is a large-scale critique about the concept of PM, the idea that if you understand the biological mechanism of disease you can target that for treatment. I think that it's a strong concept that is widely accepted. What the critics really focus on is the use of PM at a population level. They need to see the clinical advantages to the full population of patients with a given disease – for example, breast cancer. Will we see benefits by using this technology and using this therapeutic target at a population level? Will it bring down costs? Will it incur higher costs and does the cost equal the benefit we're getting? These are the questions that critics are asking.

To those critics I would say, like any system, we need to develop the regular use of PM so it can be implemented most effectively and efficiently in order to fully realise its value to both the patient and the population. What we're seeing are practice gaps – the reluctance to use the technology until the value of the technology is clear. As we develop the evidence of PM's value and implement the supporting technology, we'll begin to see those population level value elements come to the fore. We're clearly seeing individual level benefits. To realise these individual patient level value elements benefits at a population level we need to implement the system more fully and effectively and that will come with time, I'm certain.

Where does PM have the most near-term potential?

That will depend on each condition and how rapidly new technologies are developed and implemented. I feel that within five to ten years, PM will be a standard of care in three areas in particular: oncology, inherited rare diseases and pharmacogenetics. In areas such as cardiology, asthma, Alzheimer's, multiple sclerosis and in other autoimmune diseases, we are also seeing the advance of PM.

What are the pitfalls?

The real danger is that PM science is moving more rapidly than policy, so if we don't develop and implement policies for both regulatory approval and coverage and reimbursement, we'll see an unnecessarily slow implementation of PM. This would be to the detriment of patients. We need sound regulatory oversight and reimbursement policies in place.

How will PM become more accepted in the world of medicine?

What critics are looking for is evidence that PM has value. We need practice-based evidence. Research only goes so far and the sector needs to know how PM is going to work in practice. These are the steps now being taken.